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09/868,889	09/14/2001	Jon Hangeland	102241-101	6789

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05/07/2003

Wiggin & Dana
Intellectual Property Law Section
One Century Tower
New Haven, CT 06508-1832

EXAMINER

COPPINS, JANET L

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 05/07/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,889

Applicant(s)

HANGELAND ET AL.

Examiner

Janet Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-14 and 19-29 is/are rejected.
- 7) ☒ Claim(s) 3,4,17,18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-29 pending in the instant application.

Election/Restrictions

1. Receipt is acknowledged of Applicants' Response to the Restriction Requirement, submitted 2/10/03, which has been reviewed by the Examiner and entered of record in the file.
2. Applicants have elected Group IV, drawn to compounds wherein R4 is a carboxylic acid amide. Claims 1-14 (in part), claims 15 and 16, and claims 17-19 (in part) drawn to compounds wherein R4 is a heteroaromatic moiety, an amine, or an acylsulfonamide withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 7.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

4. Claims 3, 4, 17, and 18 objected to as being dependent on rejected base claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23, 24, and 28 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent for treating diseases associated with metabolism dysfunction, utilizing a stabilized pharmaceutical composition containing thyroid receptor ligands, does not reasonably provide enablement for an agent which prevents such diseases through use of the composition. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

7. In the instant case, applicants are claiming a compound that is an agent for “preventing” diseases associated with metabolism dysfunction, or diseases dependent on the expression of a T₃ regulated gene. The nature of the invention is of a pharmaceutical for the *treatment* of a disease, i.e. obesity, hypercholesterolemia, atherosclerosis, depression, osteoporosis, hypothyroidism, etc. As stated, however, the claim asserts that the compound is capable of *preventing* such diseases, or to keep from happening. The state of the art does not teach the absolute prevention of diseases or disorders. Thus any claim to the prevention of the disclosed diseases (claim 24) is highly unpredictable given the current state of the art. Furthermore, applicant states that the invention may be used in the prevention of diseases associated with metabolism dysfunction or dependent on the expression of a T₃ regulated gene (please see specification, page 14) but does

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not provide any examples as such in the specification. Because neither the prior art nor the current application provide sufficient guidance to one of ordinary skill in the art as to the prevention of diseases associated with metabolism dysfunction, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 25, 26, and 29 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility. Claims 25, 26, and 29 are directed to nonstatutory subject matter. The aforementioned claims are drafted in terms of “use”, however “use” is not one of the statutory classes of invention. Please see *Clinical Products v. Brenner*, 149 USPQ 475, 476 (1966). Accordingly, the claims have not been further treated on the merits.

10. Claims 25, 26, and 29 also rejected under 35 U.S.C. 112, first paragraph (please see *In re Wands*, above). Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

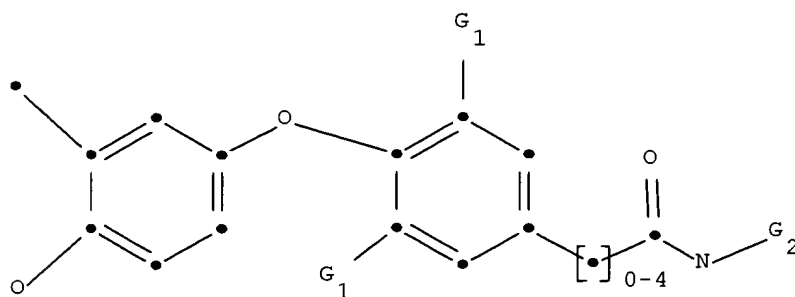
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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

12. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

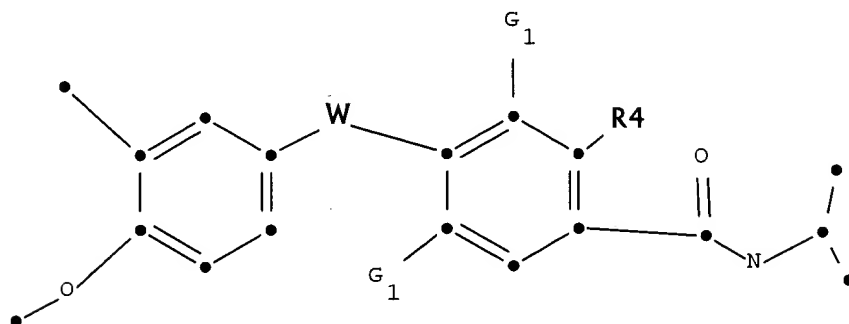
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 2, 5-14, and 19-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-15, and 17-23 of U.S. Patent No. 6,395,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicants are claiming thyroid receptor ligands according to general formula I:



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while the '784 patent claims thyroid receptor ligands according to their general formula I:



It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to modify the thyroid receptor ligand of the '784 patent, employing an oxygen for the W variable, wherein R₄ is a methyl group (which is known in the art to be equivalent to a hydrogen substitution, and would not affect the activity of the claimed compound). The above compound is specifically described in the table found in column 20 of the '784 patent, which teaches preferred embodiments of the reference patent's general formula I, which also read on the instant application. One of skill in the art would have recognized that both the '784 patent and the instant claimed compounds have the same utility, thyroid receptor ligands which are useful for treating diseases associated with metabolism dysfunction. Therefore one skilled in the art would have been motivated to employ the genus compounds of general formula I of the '784 patent with the expectation of obtaining a similar genus of thyroid receptor compounds, that possess the same activity and are useful for the same utility.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Coppins whose telephone number is 703.308.4422. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703.308.4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703.746.9037 for regular communications and 703.872.9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1235.

Janet L. Coppins
May 5, 2003



CEILA CHANG
PRIMARY EXAMINER
GROUP 1200-625

For Alan Rotman
SPZ AU 1625